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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,349	09/12/2005	Atsushi Nagasawa	0230-0219PUS1	5681
2292 7590 07/13/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER BADR, HAMID R				
ART UNIT		PAPER NUMBER		
1794				
NOTIFICATION DATE		DELIVERY MODE		
07/13/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/520,349

Applicant(s)

NAGASAWA, ATSUSHI

Examiner

HAMID R. BADR

Art Unit

1794

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 23-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' amendment after the final rejection filed on 6/17/2009 is acknowledged. The after final amendment has been entered and the finality of the previous office action has been withdrawn.

Upon reconsideration, a new rejection is being set forth with respect to claims 20, 23-24.

Claims 20, 23-24 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 20, and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,
- (d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Nakagawa et al. (1994, Construction from a single parent of baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1).

4. R1 studies the hybridization of spores of *Saccharomyces cerevisiae* (commercial baker's yeast) to construct a baker's yeast which is freeze-tolerant and has fermentative activity in both lean and sweet doughs (Abstract).

5. R1 teaches determining the mating types to be used for their hybridization process (Page 3500, Col. 1, Determination of mating type).

6. R1 discloses the process of construction of hybrids. The isolated haploid strains showing opposite mating types are crossed by mixing in liquid medium. After the hybridization process, isolated strains are checked for their sporulation ability. Spore forming isolates are considered hybrids. (Page 3500, Col. 1, construction of hybrids)

7. R1 gives details of dough ingredients for lean, regular and sweet doughs. A commercial hard wheat flour is used having 12% protein and 0.36% ash (Page 3500, Col. 1 ingredients of doughs and Table 1).
8. Given that R1 discloses the suitability of the developed strain of yeast for lean, regular and sweet doughs, it is clear that the fermentability of such doughs will be in the same range as presently claimed.
9. R1 teaches the dough raising test by measuring the carbon dioxide evolved after 2 hours at 30°C. (Page 3500, Col.1 dough raising test)
10. R1 explains the frozen dough system where the prepared doughs are stored at -20°C for 1 week. After the freezing period, the thawed dough is placed in a bottle of Fermograph and the dough raising activity is measured for 2 hours. (Page 3500, Col. 1 Frozen dough system)
11. R1 indicates that it is possible to obtain strains with more improved qualities such as leavening ability and freeze tolerance than the commercial baker's yeast now available. (Page 3502, Col. 1, lines 13-17)
12. R1 is silent regarding *Saccharomyces cerevisiae* strain FT-4 (FERM BP-8081).
1. R1 discloses the construction of a baker's yeast, *Saccharomyces cerevisiae*, which has high freeze tolerance, and high fermentative activity in both lean and sweet doughs. Paragraphs 4-7 above, summarize the hybridization process for creating the new strain of baker's yeast which is both freeze and high sugar tolerant. Furthermore, the use of *Saccharomyces cerevisiae* as baker's yeast, its incorporation into bread dough and baking the dough to produce a baked product such as bread, as presently

claimed, is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to create a strain of baker's yeast to be freeze and high sugar tolerant as disclosed by R1. One would do so to create a baker's yeast which can maintain its fermentative ability after the dough is thawed from a frozen state. Such a yeast would be useful in formulations of high sugar content. Absent any evidence and based on the teachings of the cited reference, there would be a reasonable expectation of success in developing such strain of baker's yeast. Although R1 does not disclose the same process, it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

Therefore, absent evidence of criticality regarding the presently claimed strain and given that R1 meets the requirements of the claimed *Saccharomyces cerevisiae*, R1 clearly meet the requirements of present claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794